

Amendment No. 2 to HB0143

Sexton C
Signature of Sponsor

AMEND Senate Bill No. 811

House Bill No. 143*

by adding the following language immediately after the language “food and drug administration” in § 63-6-302(2)(B) in Section 1:

, and is unable to enter, or be accepted within one (1) week after applying to, a clinical trial within fifty (50) miles of the individual’s home

AND FURTHER AMEND by adding the following as a new, appropriately designated subdivision in § 63-6-302 in Section 1 and redesignating the remaining subdivisions:

() “Adverse event” means any untoward medical occurrence associated with the use of an investigational drug, biological product, or device in humans, regardless if drug-related;

AND FURTHER AMEND by adding the following language as a new section in the amendatory language of Section 1:

63-6-309. If a patient suffers an adverse event associated with the use of an investigational drug, biological product, or device, the patient’s physician shall report the adverse event to the manufacturer of the investigational drug, biological product, or device.